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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO.       |
|---|-------------|----------------------|-------------------------------|------------------------|
| 10/804,583  | 03/18/2004  | Edgardo Costa Maiani | DID1046US                     | 7264                   |
| 9561 7590 05/30/2008<br>POPOVICH, WILES & O'CONNELL, PA<br>650 THIRD AVENUE SOUTH<br>SUITE 600<br>MINNEAPOLIS, MN 55402 |             |                      | EXAMINER<br>CHAPMAN, GINGER T |                        |
|   |             |                      | ART UNIT<br>3761              | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>05/30/2008       | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/804,583

**Applicant(s)**

MAIANTI ET AL.

**Examiner**

Ginger T. Chapman

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 7 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-3 and 7 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

#### **Status of the claims:**

Claims 4-6 are cancelled, claim 7 is added; claims 1-3 and 7 are pending in the application.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Raible (US 5,770,149).

With regard to claim 1, as seen in Figures 8, and 8a, Raible discloses an integrated device (c. 1, l. 67) for oxygenating and filtering blood flowing through an extracorporeal blood circuit (10) comprising: a bubble trap (fig. 8: 122) having an inlet (fig. 3: 28; fig. 8: 118) for receiving venous blood and an outlet (88; 88a) for supplying venous blood; a blood pump (fig 3: 40; fig. 9:40a) having an inlet connected to receive venous blood (30) and an outlet (52); a heat exchanger (54) having an blood inlet (60) connected to receive venous blood from the outlet of the pump (40) and a blood outlet (70) for supplying temperature controlled venous blood; an oxygenator (72) having an inlet (70) connected to receive venous blood from the outlet (70) of the heat exchanger (54) and an outlet for supplying oxygenated blood; an arterial filter (128)

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having an inlet (126) connected to receive oxygenated blood from the outlet of the oxygenator (72) and an outlet (88b) for supplying filtered oxygenated blood; and a monolithic housing (12) including a first portion for defining the bubble trap, a second portion for defining the blood pump, a third portion for defining the heat exchanger, a fourth portion for defining the oxygenator and a fifth portion for defining the arterial blood filter ("R/P/HE/MO": c. 12, l. 14; "M/D": c. 9, l. 45-47).

With regard to claim 2, Raible discloses a centrifugal pump (40).

With respect to claim 7, as best depicted in Figures 8 and 9, Raible teaches blood flowing through the circuit is directed through bubble trap (122) before the blood enters the blood pump ((40a) c. 12, ll. 30-50).

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raible in view of Israelev (US 5,924,848).
5. With regard to claim 3, Raible discloses the claimed invention except for the axis of the pump is horizontal. Israelev teaches a centrifugal pump for extracorporeal blood circuit in which the axis of the pump may be horizontal or vertical (c. 3, ll. 58-59. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the pump of Israelev in the circuit of Raible since Israelev states, at c. 3, ll. 54-60 that the benefit of using such a pump is that it is stable when the direction of the pump's axis of rotation is changed because the position of the housing is changed to allow for flexibility in positioning the pump.

#### ***Double Patenting***

6. Claims 1-3 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-5 of copending Application No. 10/805,165. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a bubble trap, blood pump, heat exchanger, oxygenator, blood filter, housing; the copending claims recite a blood reservoir, blood pump, heat exchanger, oxygenator, blood filter, housing. Thus, were these applications not by the same inventive entity, the earlier filed application could be used as a rejection under 35 USC 102 because the only difference is the recitation of the bubble trap, the bubble trap comprises a reservoir for blood, therefore the claims are not patentably distinct and therefore are subject to a double patenting rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

Applicant's arguments with respect to claims 1-3 and 7 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/  
Examiner, Art Unit 3761  
5/23/08

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761